approval. Thoracoscopic treatment of the LAA has been suggested as a sole therapy for patients with AF to minimize stroke risk.[8] There is evidence to suggest that the AtriClip device results in electrical isolation, and the device has been used as an isolated therapy for focal atrial tachycardia.[21]

Although the device studied is third generation, the deployment tool was a first-generation instrument. This reusable large deployment tool was cumbersome and can be used only via a sternotomy. There are 2 currently approved deployment tools. One is designed for open sternotomy, and the other is used for thoracoscopic approach. Both are smaller and more flexible, and have a lower profile than the deployment tool used in this report.

Limitations

This study is limited in the short-term imaging follow-up of only 3 months, although clinical follow-up extends to 12 months. This is a relatively small cohort of patients. Longer follow-up is needed to evaluate for evidence of device migration. This study was not designed to assess reduction in stroke risk. Late neurologic events developed in 2 patients, which did not appear to be related to the LAA to the best of our knowledge. A significantly larger randomized study would be required with longer-term follow-up to document any efficacy in stroke prophylaxis.

CONCLUSIONS

This multicenter initial trial suggests that exclusion of the LAA can be performed safely and without injury to the heart or surrounding structures during open cardiac surgery with the AtriClip device. In short-term follow-up, there is evidence of persistent LAA closure with no communication to the appendage. Long-term studies should be performed to evaluate the efficacy in the prevention of stroke and rule out the potential for device migration.

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Discussion

Dr Bryan Meyers *(St Louis, Mo)*. There was a long list of inclusion and exclusion criteria. How restrictive was this trial and how representative is this patient population compared with the group of patients you encounter every day in your cardiac surgery practice?

Dr Ailawadi. On the basis of the exclusion criteria from this study, I would say approximately half of the patients I see in daily practice could have qualified for this. The most liberal of the inclusion criteria was age greater than 65 years and hypertension. So many of the patients we treat meet that criteria in this trial.

Dr Wiley Nifong *(Greenville, NC)*. Great study, great results. We have been very happy using the clip clinically as well. I did

notice early in the learning curve it looked like there were 3 misfires. Of course, while you are using it, you can get it down seated well. It appears, in the beating heart, to guide itself down. After it fires, I assume you could just use a wire cutter? You could remove it if you placed it and noticed it was not seated correctly, is that correct?

Dr Ailawadi. There are a couple of points to mention about deploying the device. The deployment device we used in this study was a large metal reusable tool, with a manual release. Once you release it, it is difficult, but it can be removed. You do not need a wire cutter, but you essentially take 2 pick-ups, separate the clip, and pull it off and then reattach it to the deployment tool and put it on again. The current FDA-approved device has a mechanism to open and close, and once you are happy with positioning, then you go ahead and cut the 4 sutures. So the current deployment device allows repositioning until it is in optimal position.

Dr Azhar Hossain *(Indianapolis, Ind)*. How do you determine that you have been successful in excluding the entire appendage? As you know, there is residual appendage left, and the risk of thrombosis is still present. So are you using TEE assistance during the procedure?

Dr Ailawadi. It certainly can be done. I can tell you that during a sternotomy when you have the heart lifted up, it can be challenging to visualize by TEE. So in this situation, clip placement is by visual inspection. We do use TEE routinely in all of our cases. I have also performed this multiple times via a minimally invasive approach when performing a hybrid AF procedure or thoracoscopic AF procedure. In this situation, the heart is in its native position, and we can visualize by TEE before we deploy the clip.

Dr Bryan Meyers *(St Louis, Mo)*. So you showed efficacy in the ability to exclude the appendage. The next step is going to be to show clinical effectiveness, and you are going to need a huge trial, aren't you, for the rare events you are trying to prevent?

Dr Ailawadi. Correct.

Dr Meyers. Any idea of where that is going next?

Dr Ailawadi. This is the million dollar question. I suspect it will require a large trial of at least 2000 patients. We will need to see what type of funding is available for this type of study. Ultimately, this will be required, not just with this particular device but with all the devices to see the clinical effectiveness of stroke reduction.